Medical Policy

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Title: Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

Related Policies:	▪ *Low Intensity Pulsed Ultrasound Fracture Healing Device* ▪ *Electrical Bone Growth Stimulation of the Appendicular Skeleton* ▪ *Lumbar Spinal Fusion*

Professional / Institutional
Original Effective Date: January 1, 2009
Latest Review Date: July 8, 2025
Current Effective Date: June 9, 2017

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Populations	Interventions	Comparators	Outcomes
Individuals: • Who are at high risk of lumbar spinal fusion surgery failure	Interventions of interest are: • Invasive electrical bone growth stimulation	Comparators of interest are: • Lumbar spinal fusion surgery without electrical bone growth stimulation	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes
Individuals: • Who are at high risk of lumbar	Interventions of interest are: • Invasive electrical bone growth stimulation	Comparators of interest are: • Lumbar spinal fusion surgery without	Relevant outcomes include: • Symptoms

Populations	Interventions	Comparators	Outcomes
spinal fusion surgery failure		electrical bone growth stimulation	• Change in disease status • Functional outcomes
Individuals: • With failed lumbar spinal fusion surgery	Interventions of interest are: • Noninvasive electrical bone growth stimulation	Comparators of interest are: • Surgery • Conservative management	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes
Individuals: • Who are undergoing cervical spinal fusion surgery or have failed cervical spine fusion	Interventions of interest are: • Invasive or noninvasive electrical bone growth stimulation	Comparators of interest are: • Cervical spinal fusion surgery without electrical bone growth stimulation • Conservative management	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes

DESCRIPTION

Both invasive and noninvasive electrical bone growth stimulators have been investigated as an adjunct to spinal fusion surgery, with or without associated instrumentation, to enhance the probability of obtaining a solid spinal fusion. Noninvasive devices have also been investigated in patients who are at normal risk of failed fusion and to treat a failed fusion.

OBJECTIVE

The objective of this evidence review is to determine whether the use of electrical bone growth stimulation improves bone fusion rates in individuals at risk for spinal fusion failure.

BACKGROUND

Electrical Bone Growth Stimulators

Both invasive and noninvasive electrical bone growth stimulators have been investigated as an adjunct to spinal fusion surgery, with or without associated instrumentation, to enhance the probability of obtaining a solid spinal fusion. Noninvasive devices have also been investigated to treat a failed fusion.

Electrical and electromagnetic fields can be generated and applied to bones through surgical, noninvasive, and semi-invasive methods.

Invasive Stimulators

Invasive devices require surgical implantation of a current generator in an intramuscular or subcutaneous space, with an accompanying electrode implanted within the fragments of bone graft at the fusion site. The implantable device typically remains functional for 6 to 9 months after implantation. Although the current generator is removed in a second surgical procedure when stimulation is completed, the electrode may or may not be removed. Implantable

electrodes provide constant stimulation at the nonunion or fracture site but carry increased risks associated with implantable leads.

Noninvasive Stimulators
Noninvasive electrical bone growth stimulators generate a weak electrical current within the target site using either pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. In capacitive coupling, small skin pads/electrodes are placed on either side of the fusion site and are worn for 24 hours a day until healing occurs, or for up to 9 months. In contrast, pulsed electromagnetic fields are delivered via treatment coils that are placed into a back brace or directly onto the skin and are worn for 6 to 8 hours a day for 3 to 6 months. Combined magnetic fields deliver a time-varying magnetic field by superimposing the time-varying field onto an additional static magnetic field. This device involves 30 minutes of treatment daily for 9 months. Patient compliance may be an issue with externally worn devices.

Semi-Invasive Stimulators
Semi-invasive (semi-implantable) stimulators use percutaneous electrodes and an external power supply, obviating the need for a surgical procedure to remove the generator when treatment is finished.

REGULATORY STATUS

Table 1 summarizes the FDA cleared or approved noninvasive and implantable electrical bone growth stimulator devices. No semi-invasive electrical bone growth stimulator devices with the FDA approval or clearance were identified.

The FDA has approved labeling changes for electrical bone growth stimulators that remove any time frame for the diagnosis. In September 2020, FDA considered the reclassification of noninvasive electrical bone growth stimulators from Class 3 to the lower-risk Class 2 category.[1,] As of March 2025, however, the devices remain Class 3.

FDA product codes: LOE (invasive bone growth stimulator), LOF (noninvasive bone growth stimulator).

Table 1. U.S. Food and Drug Administration-Approved Electrical Bone Growth Stimulator devices

Device	Indication	Manufacturer	Date Approved	PMA No.
Noninvasive Electrical Bone Growth Stimulators				
BIO Osteogen System 204 (now EBI Bone Healing System)	• Indicated for the treatment of a variety of conditions, including non-unions, congenital pseudarthrosis, and certain fractures. • A pulsed electromagnetic field system. The device is secured with a belt around the waist.	EBI, LLC (now Highridge Medical)	1979	P790002
SpinalPak® Non-invasive Spine Fusion Stimulator System	• Indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels • A capacitive coupling system, approved for use as an adjunct to primary lumbar spinal fusion at 1 or 2 levels.	EBI, LLC (now Highridge Medical)	1986	P850022/S017
SpinaLogic Bone Growth Stimulator®	· Indicated as an adjunct electromagnetic treatment to primary lumbar spinal fusion surgery for one or two levels.· Approved as a combined magnetic field portable device. This device is secured with a belt around the waist.	DJO (now Enovis)	1994	P910066
Spinal-Stim	• Indicated as a spinal fusion adjunct to increase the probability of fusion success and as a nonoperative treatment for salvage of failed spinal fusion, where a minimum of nine months has elapsed since last surgery.	Orthofix	1996	P850007/S027
Cervical-Stim Model 505L Cervical Fusion System	• Indicated as an adjunct to cervical fusion surgery in patients at high risk for non-fusion • A pulsed electromagnetic field system, was approved as an adjunct to cervical fusion surgery in patients at high-risk for nonfusion.	Orthofix	2004	P030034
ActaStim-S Spine Fusion Stimulator	• Indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels	Theragen, Inc.	2020	P190030
Xstim Spine Fusion Stimulator	• Indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels	Xstim	2024	P230025

Device	Indication	Manufacturer	Date Approved	PMA No.
Implantable Electrical Bone Growth Stimulators				
OsteoStim	• OsteoStim® (Electro-Biology), which may also be marketed under the trade name SPF (Biomet) was approved	EBI, LLC (now Highridge Medical)	1980	P79000
SpF Implantable Spinal Fusion Stimulator	• Indicated as a spinal fusion adjunct to increase the probability of fusion success	EBI, LLC (now Highridge Medical)	1987	P850035

POLICY

A. Either invasive or noninvasive methods of electrical bone growth stimulation may be considered **medically necessary** as an *adjunct* to **lumbar** spinal fusion surgery in individuals at high risk for fusion failure, defined as any one of the following criteria:
   1. one or more previous failed spinal fusion(s)
   2. grade 3 or worse spondylolisthesis
   3. fusion to be performed at more than 1 level
   4. current tobacco use
   5. diabetes
   6. renal disease
   7. alcoholism
   8. steroid use

B. Noninvasive electrical bone growth stimulation may be considered **medically necessary** as a treatment for individuals with failed **lumbar** spinal fusion surgery. Failed spinal fusion is defined as a spinal fusion that has not healed at a minimum of 6 months after the original surgery, as evidenced by serial radiographs over a course of 3 months.

C. Semi-invasive electrical bone growth stimulation is considered **experimental / investigational** as an adjunct to **lumbar** spinal fusion surgery and for failed **lumbar** fusion.

D. Invasive, semi-invasive, and noninvasive electrical bone growth stimulation are considered **experimental / investigational** as an adjunct to **cervical** fusion surgery and for failed cervical spine fusion.

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

RATIONALE

The evidence review was created using searches of the PubMed database. The most recent literature update was performed through April 4, 2025.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For

some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

INVASIVE ELECTRICAL BONE GROWTH STIMULATION IN INDIVIDUALS AT HIGH-RISK OF LUMBAR SPINAL FUSION SURGERY FAILURE

Clinical Context and Therapy Purpose

The purpose of invasive electrical bone growth stimulation in individuals at high risk of lumbar spinal fusion surgery failure is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of invasive electrical bone growth stimulation improve the net health outcome in individuals at high risk of lumbar spinal fusion surgery failure?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest are individuals at high risk of lumbar spinal fusion surgery failure.

Interventions

The therapy being considered is invasive electrical bone growth stimulation.

Comparators

The following practice is currently being used to treat individuals at high risk of lumbar spinal fusion surgery failure: lumbar spinal fusion surgery without invasive electrical bone growth stimulation.

Outcomes

The general outcomes of interest are symptoms, change in disease status, and functional outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

RANDOMIZED CONTROLLED TRIALS

Instrumented Spinal Fusion

Kucharzyk (1999) reported on a controlled, prospective, nonrandomized trial of implantable electrical stimulation in patients undergoing instrumented posterior spinal fusion with pedicle screws.[2,] A series of 65 patients who did not receive electrical stimulation were compared with a later series of similar patients who did receive implantable electrical stimulation. The fusion success rate was 95.6% in the stimulated group and 87% in the nonstimulated group, a statistically significant difference. It appears that all patients had at least 1 or more high-risk factors for failed fusion, including smoking history, prior surgery, multiple fusion levels, and diabetes. While this trial supported the use of electrical stimulation as an adjunct to instrumented posterior lumbar fusion, it did not specifically identify the outcomes in patients considered to be at low-risk for failed fusion.

Rogozinski and Rogozinski (1996) reported on the outcomes of 2 consecutive series of patients undergoing posterolateral fusions with autologous bone graft and pedicle screw fixation.[3,] The first series of 41 patients was treated without electrical bone growth stimulation, while the second group of 53 patients received invasive electrical stimulation. Those receiving electrical stimulation reported a 96% fusion rate, compared with an 85% fusion rate in the nonstimulated group. The fusion rate for patients receiving stimulation versus no stimulation was also significantly higher among those considered at high- risk due to previous back surgery or multiple fusion levels. No significant increase in the fusion rate was noted among nonsmokers (ie, without a risk factor), but comparative fusion rates for all patients without high-risk factors were not presented.

Noninstrumented Spinal Fusion

Andersen et al (2009) published 2-year radiographic and functional outcomes from a European multicenter RCT of direct current (DC) stimulation with the SpF Implantable Spinal Fusion Stimulator (SpF-XL IIb) for posterolateral lumbar spinal fusion in 98 patients older than age 60 years.[4,] This age group has decreased fusion potential. Also, instrumentation was not used due to risks related to longer operating times and screw loosening due to osteoporosis. All patients received fresh frozen allograft bone mixed with autograft obtained from the decompression procedure and were braced for months after surgery. Dummy electrodes were placed in the control group to allow blinded radiographic evaluation, but patients and surgeons were not blinded to treatment group. Stimulator-specific complications included 3 cases of hematoma after removal of the battery and 2 patients with pain at the site of the subcutaneous pocket. Three patients dropped out before the 1-year radiologic evaluation, 1 patient died, and 25 other patients did not complete the functional outcome questionnaires, resulting in 70% follow-up at 2 years. The percentage of dropouts was similar for both treatments; patients who missed their 2-year evaluation had poorer outcomes on the Dallas Pain Questionnaire at the 1-year follow-up. Blinded evaluation of fusion by computed tomography scan indicated the same low percentage of cases with fusion in both groups (33%). Fusion rates by plain radiographs were 57% (24/42) in the control group and 64% (27/42) in the standard direct current (DC)-stimulation group. Patients who achieved solid fusion had a better functional outcome and lower pain scores at their last follow-up. At 2-year follow-up, electrical stimulation was associated with improved functional outcomes on 3 of 4 Dallas Pain Questionnaire subscales (daily activity, work/leisure, social

interest) but not for the Low Back Pain Rating Scale or the 36-Item Short-Form Health Survey. These functional results have a high potential for bias due to the dropout rate among patients with poorer outcomes and the unequal patient expectation in this unblinded study.

Andersen et al (2010) evaluated the bone quality of the fusion mass in 80 (82%) of 98 the patients previously described who underwent dual-energy x-ray absorptiometry scanning to evaluate bone mineral density at the 1-year follow-up.[5,] This report described 40 (n=36) and 100 (n=8) microampere (μA) DC-stimulation compared with a nonstimulated control condition (n=36). Fusion rates determined by computed tomography scanning at the 2-year follow-up were 34% in the control group and 34% and 43% in the 40 and 100 μA groups, respectively (p= not significant). Patients classified as fused after 2 years had significantly higher fusion mass bone mineral density at 1 year (0.592 g/cm^2 vs 0.466 g/cm^2), but DC electrical stimulation did not improve fusion mass bone quality (0.483 g/cm^2 for 40 μA vs 0.458 g/cm^2 for 100 μA vs 0.512 g/cm^2 for controls). Using linear regression, fusion mass bone quality was significantly influenced by sex, patient age, bone density of the remaining part of the lumbar spine, amount of bone graft applied, and smoking status.

Section Summary: Invasive Electrical Bone Growth Stimulation in Individuals at High-Risk of Lumbar Spinal Fusion Surgery Failure
Two RCTs have evaluated implantable electrical stimulation for bone growth stimulation, 1 in instrumented spinal fusion and 1 in noninstrumented spinal fusion, in patient populations at risk for failed fusion surgery. Although the studies had some risk for bias due to differential dropout rates, both showed improved fusion with electrical stimulation on blinded intermediate measures of radiographic fusion. These findings support the conclusion of improved functional outcomes with electrical stimulation.

NONINVASIVE ELECTRICAL BONE GROWTH STIMULATION IN INDIVIDUALS AT HIGH-RISK OF LUMBAR SPINAL FUSION SURGERY FAILURE

Clinical Context and Therapy Purpose
The purpose of noninvasive electrical bone growth stimulation in individuals at high risk of lumbar spinal fusion surgery failure is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of noninvasive electrical bone growth stimulation improve the net health outcome in individuals at high risk of lumbar spinal fusion surgery failure?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest are individuals at high risk of lumbar spinal fusion surgery failure.

Interventions
The therapy being considered is noninvasive electrical bone growth stimulation.

Comparators
The following practice is currently being used to treat individuals at high risk of lumbar spinal fusion surgery failure: lumbar spinal fusion surgery without noninvasive electrical bone growth stimulation

Outcomes
The general outcomes of interest are symptoms, change in disease status, and functional outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Systematic Reviews
Akhter et al (2020) conducted a meta-analysis to assess the efficacy of postoperative electrical stimulation compared to no stimulation or placebo in fostering radiographic fusion for spinal fusion patients.[6,]The investigators searched the Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE, CINAHL and PubMed from inception to 2018. Ongoing clinical trials were also identified, and reference lists of included studies were manually searched for relevant articles. Data were pooled using the Mantel-Haenszel method. Trialists were contacted for any missing or incomplete data. Of 1184 articles screened, 7 studies (6 from the US and 1 from Denmark) were eligible for final inclusion (n = 941). A total of 487 patients received postoperative electrical stimulation and 454 patients received control or sham stimulation. All evidence was of moderate quality. Electrical stimulation (pulsed electromagnetic fields, direct current, and capacitive coupling) increased the odds of a successful fusion by 2.5-fold relative to control (OR=2.53, 95% CI 1.86 to 3.43, p<.00001). Subgroup analyses by stimulation type, smoking status, and the number of levels fused showed no significant interaction. The investigators concluded that this meta-analysis found moderate-level evidence supporting the use of postoperative electrical stimulation as an adjunct to spinal fusion surgery. Patients who received postoperative electrical stimulation exhibited markedly higher rates of successful radiographic fusions compared to those who received sham, placebo-controlled, or no stimulation.

Table 2. Characteristics of RCTs in Akhter et al (2020) Meta-Analysis

Study	Country	Intervention (n)	Control (n)	Outcomes reported	Follow-up
Anderson (2009)[7,4,]	Denmark	SpF Implantable Spinal Fusion Stimulator (44)42	Dummyelectrodes,identical (33)42	Radiographic fusion rate, Dallas Pain Questionnaire, SF36, Low Back Pain Rating Scale, walking distance	24 months
Foley (2008)[8,]	USA	Cervical-Stim (163)	Inactive sham device (160)	Radiographic fusion rate, Mean visual analog scale, mean neck disability index, SF-12 physical health mean score	12 months
Goodwin (1999)[9,]	USA	SpinalPak (85)	Inactive sham device (94)	Radiographic & clinical fusion rate	12 months
Jenis (2000)[10,]	USA	SpinalStim (22)Implanted SpF2T stimulator (17)	Control (22)	Radiographic fusion grade, fusion mass bone density	12 months
Kane (1988) [11,]	USA	Osteostim HS11 (31)	No implanted stimulator (28)	Radiographic fusion rate	18 months
Linovitz et al (2002)[12,]	USA	SpinaLogic (97)	Inactive sham device (104)	Radiographic fusion rate	9 months
Mooney (1990) [13,]	USA	Custom design stimulator (based on testing on rabbits) (98)	Inactive sham device (97)	Radiographic fusion rate	12 months

Table 3. Fusion Rate Results of RCTs in Akhter et al (2020) Meta-Analysis

Study	Treatment Fusion Rate (%)	Control Fusion Rate (%)	P-Value
Anderson (2009)[7,4,]	64% (12 months); 35% (24 months)	57% (12 months); 36% (24 months)	NS (12 months); NS (24 months)
Foley (2008)[8,]	84% (6 months); 93% (12 months)	69% (6 months); 87% (12 months)	.007 (6 months); NS (12 months)
Goodwin (1999)[9,]	85%	65%	.004
Jenis (2000)[10,]	97%	95%	NS
Kane (1988) [11,]	81%	54%	.026
Linovitz et al (2002)[12,]	64%	43%	.003
Mooney (1990) [13,]	92%	65%	>.005

NS: not significant

RANDOMIZED CONTROLLED TRIALS

Section Summary: Noninvasive Electrical Bone Growth Stimulation in Individuals at High-Risk of Lumbar Spinal Fusion Surgery Failure

A meta-analysis of 7 RCTs provided moderate-level evidence that postoperative electrical stimulation effectively promotes radiographic fusion in spinal fusion patients. Those who received electrical stimulation showed significantly higher fusion success rates compared to those receiving sham, placebo, or no stimulation.

NONINVASIVE ELECTRICAL BONE GROWTH STIMULATION IN INDIVIDUALS WITH FAILED LUMBAR SPINAL FUSION SURGERY

Clinical Context and Therapy Purpose

The purpose of noninvasive electrical bone growth stimulation in individuals with failed lumber spinal fusion surgery is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of noninvasive electrical bone growth stimulation improve the net health outcome in individuals with failed lumbar spinal fusion surgery?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest are individuals with failed lumbar spinal fusion surgery.

Interventions

The therapy being considered is noninvasive electrical bone growth stimulation.

Comparators
The following practice is currently being used to treat individuals with failed lumbar spinal fusion surgery: lumbar spinal fusion surgery without noninvasive electrical bone growth stimulation

Outcomes
The general outcomes of interest are symptoms, change in disease status and functional outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
A TEC Assessment (1993) evaluated noninvasive electrical bone stimulation as a treatment of failed spinal fusion surgery (ie, salvage therapy).[14,] The TEC Assessment concluded that data from uncontrolled studies of patients with failed spinal fusion surgery suggested that noninvasive electrical stimulation results in a significantly higher fusion rate. The lack of controlled clinical trials was balanced by the fact that these patients served as their own controls.

Section Summary: Noninvasive Electrical Bone Growth Stimulation in Individuals With Failed Lumbar Spinal Fusion Surgery
A TEC Assessment of uncontrolled studies suggested that noninvasive electrical stimulation results in a significantly higher fusion rate than no electrical stimulation in patients with failed lumbar spinal fusion surgery.

INVASIVE OR NONINVASIVE ELECTRICAL BONE GROWTH STIMULATION IN CERVICAL SPINAL FUSION SURGERY

Clinical Context and Therapy Purpose
The purpose of electrical bone growth stimulation in cervical spinal fusion surgery is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of electrical bone growth stimulation improve the net health outcome in individuals undergoing cervical spinal fusion surgery or with failed cervical spinal fusion surgery?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest are individuals undergoing cervical spinal fusion surgery or with failed cervical spinal fusion surgery.

Interventions
The therapy being considered is invasive or noninvasive electrical bone growth stimulation.

Comparators
The following practice is currently being used to treat individuals undergoing cervical spinal fusion surgery or with failed cervical spinal fusion surgery: cervical spinal fusion surgery without electrical bone growth stimulation or conservative management.

Outcomes
The general outcomes of interest are symptoms, change in disease status, and functional outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Randomized Controlled Trials
Foley et al (2008) published results from the industry-sponsored investigational device exemption trial of pulsed electromagnetic field stimulation as an adjunct to anterior cervical discectomy and fusion with anterior cervical plates and allograft interbody implants.[8,] This trial described results using the Cervical-Stim device (Orthofix) that received premarket approval from the FDA in 2004.[15,]This trial was included in the Akhter et al (2020) meta-analysis discussed above.

A total of 323 patients were randomized, 163 to pulsed electromagnetic field stimulation and 160 to no stimulation. All patients were active smokers (>1 pack of cigarettes per day, 164 patients) or were undergoing multilevel anterior cervical discectomy and fusion (192 patients). Patients with a pertinent history of trauma, previous posterior cervical approach or revision surgery, certain systemic conditions or steroid use, and regional conditions (eg, Paget disease, spondylitis) were excluded. Beginning 1 week after surgery, patients in the treatment group wore the Cervical-Stim device for 4 hours a day for 3 months.

Efficacy was measured by radiographic analysis at 1, 2, 3, 6, and 12 months. At 6 months, 122 patients in the treatment group and 118 in the control group were evaluable; 15 in the pulsed electromagnetic field group and 13 in the control group voluntarily withdrew, 7 in the pulsed electromagnetic field group and 1 control violated study protocol, and 19 in the pulsed electromagnetic field group and 28 controls had inevaluable radiographs or radiographs not taken within 2 weeks of the 6-month postoperative window. Fusion rates for the 240 (74%) evaluable patients at 6 months were 83.6% for the pulsed electromagnetic field group and 68.6% for the control group (p=0.007). By intention-to-treat analysis, assuming that nonevaluable patients did

not have fusion, pulsed electromagnetic field, and control group fusion rates were 65.6% and 56.3%, respectively; these rates did not differ significantly (p=0.084). The FDA analysis, however, indicated that the results at 6 months still differed statistically in sensitivity analysis performed with the last observation carried forward or with all missing data imputed as nonfusion. Of 245 patients available for follow-up at 12 months, fusion was achieved in 116 (92.8%) of 125 pulsed electromagnetic field patients and 104 (86.7%) of 120 control patients; these rates did not differ significantly (p=0.113). Patient compliance, which was automatically monitored by the device, was assessed at each visit; however, compliance data were not reported in the article.

Clinical outcomes were not reported in the 2008 publication but were reported to the FDA. With clinical success defined as no worsening in neurologic function, an improvement in pain assessment on the visual analog scale, and no worsening in Neck Disability Index score, the study found no statistically significant differences between groups in the percentages of subjects considered a clinical success at 6 months (p=0.85) or 12 months (p=0.11). The marginal difference in fusion rates by intention-to-treat analysis at 6 months, nonsignificant difference in fusion rates at 12 months, and lack of difference in functional outcomes at either 6 or 12 months did not support the efficacy of this device.

Uncontrolled Studies

Coric et al (2018) published results from an industry-sponsored multicenter cohort study of pulsed electromagnetic field treatment in patients at high-risk of cervical arthrodesis following anterior cervical discectomy and fusion procedures.[16,] The trial described results using the Cervical-Stim device (Orthofix) for 274 patients enrolled across 3 institutions. All patients had 1 or more risk factors, defined as nicotine user, osteoporosis, diabetes, age greater than 65 years or greater than 50 years, for pseudoarthrosis, and were treated with pulsed electromagnetic field stimulation for 3 to 6 months. A historical control group was generated from a post hoc analysis of high-risk subjects from the original U.S. Food and Drug Administration (FDA) investigational device exemption trial. The primary endpoint was bone fusion rates as assessed at 6 and 12 months by the treating surgeon not blinded to clinical symptoms and outcomes for subjects. At 6 months, statistically significant improvements in fusion rates were found for patients falling into the following risk factor groups with at least 1 risk factor for: age over 50 years and 2-level arthrodesis (p=0.002); age over 50 years and 3-level arthrodesis (p<0.001); age over 65 years and 2-level arthrodesis (p=0.009); and age over 65 years and 3-level arthrodesis (p=0.002). Likewise, at 12 months, statistically significant improvements in fusion rates were found for patients falling into the following risk factor groups with at least 1 risk factor for: age over 50 years and 2-level arthrodesis (p=0.002); age over 50 years and 3-level arthrodesis (p<0.001); age over 65 years and 2-level arthrodesis (p=0.001); and age over 65 years and 3-level arthrodesis (p<0.001). Study limitations included the use of a historical control group from the original investigational device exemption trial instead of a prospective control group, surgeons who were not blinded to clinical symptoms and outcomes, and surgeons who were not restricted to the surgical procedures used during the study.

Section Summary: Invasive or Noninvasive Electrical Bone Growth Stimulation in Cervical Spinal Fusion Surgery
One RCT evaluating electrical bone growth stimulation was identified. Due to methodologic limitations in the only controlled trial published to date, the efficacy of electrical stimulation has not yet been established. An open-label multicenter cohort study provided evidence to demonstrate that patients at high-risk for arthrodesis following anterior cervical discectomy and fusion procedures reported statistically significant improvements in fusion rates with pulsed electromagnetic field stimulation. However, limitations in the study design, including use of a historical control group, lack of blinding, and no restrictions on surgical methods used by surgeons, preclude definitive assessments of the efficacy of pulsed electromagnetic field treatment in this high-risk population. Randomized controlled trials are required to establish the effectiveness of pulsed electromagnetic field treatment to improve cervical fusion rates.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2011 Input

In response to requests, input was received from 2 physician specialty societies and 3 academic medical centers while this policy was under review in 2011. Input agreed with the criteria for high-risk of fusion failure of the lumbar spine. Input on electrical stimulation for the cervical spine was mixed; specifically, some reviewers input agreed that data do not demonstrate improved outcomes with use of electrical stimulation in cervical spine fusion surgery. Most reviewers agreed that the large number of dropouts, nonsignificant difference in fusion rates by intention-to-treat analysis, and lack of data on functional outcomes (eg, pain, return to usual activity) limited interpretation of the published study results.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

North American Spine Society

In 2016, the North American Spine Society (NASS) issued a coverage recommendation for electrical bone growth stimulators based on a systematic review of the evidence, which stated the following:[17,]

1. "For augmentation of spinal fusion in any and all regions of the spine including occipital-cervical, cervical, cervicothoracic, thoracic, thoracolumbar, lumbar and lumbosacral spinal regions in patients at high-risk for the development of pseudarthrosis (ie, nonunion) who exhibit one or more of the following:

    a. Are undergoing spinal fusion of two or more motion segments (3 vertebrae)
    b. Are undergoing a revision spinal fusion (eg, repeat surgery for a previously unhealed fusion attempt)
    c. Are smokers who cannot stop smoking in preparation for fusion due to the nature of the underlying condition (eg, acute traumatic fracture)
    d. Exhibit one or more of the following comorbidities when undergoing primary lumbar fusion:

        i. Diabetes
        ii. Inflammatory arthritis (eg, rheumatoid arthritis) that has required long-term corticosteroid therapy
        iii. Immunocompromised (eg, undergoing chemotherapy and radiation therapy to the spine, hypogammaglobulinemia, granulocytopenia, acquired immune deficiency syndrome, chronic granulomatous disease)
        iv. Systemic vascular disease
        v. Osteopenia or osteoporosis

2. In the lumbar spine, the following forms of electrical stimulation are indicated in high-risk patients with the specific techniques outlined. In all other regions of the spine, coverage for the same indications is recommended although there is less supporting evidence.

    a. DCS [direct current stimulation: electrodes implanted within or very close to the location of the desired fusion] and CCS [capacitance coupling stimulation; 2 electrodes placed on the skin over the fusion site] for posterolateral fusion using autograft and extender
    b. PEMFS [pulsed electromagnetic field stimulation: coils that produce a time-varying magnetic field around the area of the desired fusion] for lumbar interbody fusion."

American Association of Neurological Surgeons and Congress of Neurological Surgeons

In 2014, updated guidelines from the American Association of Neurological Surgeons and the Congress of Neurological Surgeons based on a systematic review that included conflict of interest declaration, indicated that there was no evidence published after their 2005 guidelines that conflicts with the previous recommendations on bone growth stimulation.[18,]

Based on a single-level II study (2009), the routine use of direct current stimulation in patients older than age 60 years was not recommended. Use of direct current stimulation was recommended as an option for patients younger than 60 years of age, based on level III and IV studies showing a positive impact on fusion rate. However, concerns about the level III study were that it was a poorly designed and poorly conducted cohort study consisting of an exceedingly small heterogeneous population of patients, and the overall recommendation was level C. There was insufficient evidence to recommend for or against the use of pulsed electromagnetic field stimulation as a treatment alternative to revision surgery in patients

presenting with pseudoarthrosis following posterolateral lumbar fusion (single-level IV study). No additional studies investigating the efficacy of capacitively coupled electrical stimulation were identified.

The 2 medical associations also issued guidelines in 2005 that stated there was class II and III evidence (nonrandomized comparative trials and case series):

"…to support the use of direct current stimulation or [capacitive coupled stimulation] for enhancing fusion rates in high-risk patients undergoing lumbar PLF. A beneficial effect on fusion rates in patients not at 'high risk' has not been convincingly demonstrated, nor has an effect been shown for these modalities in patients treated with interbody fusion. There is limited evidence both for and against the use of pulsed electromagnetic fields for enhancing fusion rates following PLF. Class II and III medical evidence supports the use of pulsed electromagnetic fields for promoting arthrodesis following interbody fusion. Although some studies have purported to demonstrate functional improvement in some patient subgroups, other studies have not detected differences. All of the reviewed studies are significantly flawed by the use of a four-point patient satisfaction scale as the primary outcome measure. This outcome measure is not validated. Because of the use of this flawed outcome measure and because of the conflicting results reported in the better-designed studies that assess functional outcome, there is no consistent medical evidence to support or refute use of these devices for improving patient outcomes."[19,]

U.S. Preventive Services Task Force Recommendations
Not applicable.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in March 2024 did not identify any ongoing or unpublished trials that would likely influence this review.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
E0748	Osteogenesis stimulator, electrical, noninvasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted

REVISIONS	
10-30-2013	Policy added to the bcbsks.com web site.
09-15-2016	Description section updated
	In Policy section: ▪ In Item A 8 removed "significant" to read "steroid use" ▪ In Item B added "growth" and revised "x-rays" to "radiographs" to read "Noninvasive electrical bone growth stimulation may be considered medically necessary as a treatment of patients with failed lumbar spinal fusion. Failed spinal fusion is defined as a spinal fusion that has not healed at a minimum of 6 months after the original surgery, as evidenced by serial radiographs x-rays over a course of 3 months." ▪ In Item C added "bone growth" to read "Semi-invasive electrical bone growth stimulation is considered…" ▪ In Item D added "bone growth" to read "Invasive, semi-invasive, and noninvasive electrical bone growth stimulation are considered…"
	Rationale section updated
	References updated
06-09-2017	Description section updated
	In Policy section: ▪ In Item B added "surgery" and in Item C added "spinal" to read "lumbar spinal fusion surgery" to create consistent wording between Items A, B, and C.
	Rationale section updated
	In Coding section: ▪ Removed ICD-10 Code: M51.07
	References updated
10-01-2017	In Coding section: ▪ Removed ICD-10 Code: M48.06 ▪ Added ICD-10 Codes: M48.061, M48.062
11-07-2018	Description section updated
	In Coding section: In Item A 2 replaced "III" with "3" to read "grade 3 or worse spondylolisthesis"

REVISIONS	
	Rationale section updated
	References updated
07-17-2019	Description section updated
	Rationale section updated
	References updated
07-17-2020	Description section updated
	Rationale section updated
	References updated
06-03-2021	Description section updated
	Rationale section updated
	References updated
06-01-2022	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Converted ICD-10 codes to code ranges
	Updated References Section
05-23-2023	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Removed ICD-10 codes
	Updated References Section
05-28-2024	Updated Description Section
	Updated Rationale Section
	Updated References Section
07-08-2025	Updated Description Section
	Updated Rationale Section
	Updated References Section

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